510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k061702

B. Purpose for Submission:

510(k) premarket notification package to manufacture and market the Dimension Vista™ System CK Calibrator

C. Measurand:

Creatine Kinase (CK)

D. Type of Test:

Not applicable

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dimension Vista™ System CK Calibrator

G. Regulatory Information:

1. Regulation section:

   862.1150 - Calibrator

2. Classification:

   Class II

3. Product code:

   Calibrator, Secondary (JIT)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The CK CAL is an in vitro diagnostic product for the calibration of creatine kinase (CK) method on the Dimension Vista™ System.

2. Indication(s) for use:

   The CK CAL is an in vitro diagnostic product for the calibration of creatine kinase (CK) method on the Dimension Vista™ System.

3. Special conditions for use statement(s):

   Not Applicable

4. Special instrument requirements:

   Dimension Vista™ Integrated System

I. Device Description:

Creatine Kinase Calibrator is a frozen liquid, bovine serum albumin based product containing creatine kinase from porcine heart. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B. The volume per vial is 1.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® Creatine Kinase Verifier

2. Predicate 510(k) number(s):

   k861700

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	To be used with CK assays.	To be used with CK assays.
Traceability	Traceable to CK Masterpool, Dimension® clinical chemistry system values.	Traceable to CK Masterpool, Dimension® clinical chemistry system values.

Differences		
Item	Device	Predicate
Intended Use	The CK CAL is an in vitro diagnostic product for the calibration of creatine kinase (CK) method on the Dimension Vista™ System.	The Dimension® Creatine Kinase Verifier is an in vitro diagnostic product to be used to verify the Dimension® clinical chemistry system for the Creatine Kinase (CK) method.
Form	Liquid	Lyophilized
Base	Bovine serum albumin based product containing creatine kinase from porcine heart.	Human serum base product containing creatine kinase from simian heart.
Levels	Two Levels	Three Levels

K. Standard/Guidance Document Referenced (if applicable):

CEN 13640, Stability Testing of In Vitro Diagnostic Reagents

ISO 14971:2000, Medical devices - Application of risk management to medical devices

FDA Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

FDA Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Not Applicable

   b. *Linearity/assay reportable range:*

      Not Applicable

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability

The assigned values of the Creatine Kinase Calibrator are traceable to Master Pool, Dimension® clinical chemistry system.

Value Assignment

The new calibrator Master Pool is made by gravimetrically adding quantities of creatine kinase to bovine serum albumin base to target concentrations. The concentrations are verified against a previously approved Master Pool lot. The final bottle value for the Master Pool is assigned for each level by testing N = 45 replicates on multiple instruments.

A stock solution is prepared for the new commercial calibrator lot by gravimetrically adding quantities of creatine kinase to bovine serum albumin base to target concentrations. The stock solution is verified by comparing the recovery of the stock solution versus the Master Pool assigned bottle values. For the commercial calibrator lot, calculated quantities of the stock solution are added to the bovine serum albumin base to target concentrations. The concentration of each level is verified to be within acceptable range by using an instrument calibrated with Master Pools. The final bottle value is assigned to each level and verified using a released commercial lot of calibrator on multiple instruments for N = 45 total replicates.

Stability

Target shelf life for the Dimension Vista™ Creatine Kinase Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at -20°C with control stored at -70°C. The method is calibrated from this stored material. The -20°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be ≤ 5 %. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.

A vial punctured by the instrument and stored on board is stable for seven days. An open vial not on instrument, but recapped and stored in a refrigerator is stable for 30 days. For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 1, 8, 15, 22, and 32 versus freshly opened vials.

d. Detection limit:

Not Applicable

e. Analytical specificity:

Not Applicable

f. Assay cut-off:

Not Applicable

2. Comparison studies:

   a. Method comparison with predicate device:
   Not Applicable

   b. Matrix comparison:
   Not Applicable

3. Clinical studies:

   a. Clinical Sensitivity:
   Not Applicable

   b. Clinical specificity:
   Not Applicable

   c. Other clinical supportive data (when a. and b. are not applicable):
   Not Applicable

4. Clinical cut-off:

   Not Applicable

5. Expected values/Reference range:

   Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.